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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,427	08/23/2006	Miranda Weggeman	2578-7869US	5466
24247	7590	04/03/2008		
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER BLUMEL, BENJAMIN P	
			ART UNIT 1648	PAPER NUMBER
			NOTIFICATION DATE 04/03/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,427	<b>Applicant(s)</b> WEGGEMAN ET AL.	
	<b>Examiner</b> BENJAMIN P. BLUMEL	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on January 4, 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 19-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/23/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Invention I in the reply filed on January 4, 2008 is acknowledged.

Claims 19-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on January 4, 2008.

Claims 1-18, 33 and 34 are examined on the merits.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on August 23, 2006 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

Applicant is also reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2002/0177215), Cook et al. (Protein Expression and Purification, 1999) and Molin et al. (US 5,173,418).

The claimed invention is drawn to a method for the purification of a recombinant adenovirus from a host cell, said method comprising in the given order the steps of:

- a) culturing host cells that are infected with adenovirus,
- b) adding benzonase to the cell culture,
- c) lysing said host cells with triton X-100 to provide a lysate comprising the adenovirus,
- d) clarification of the lysate by depth filtration, membrane filtration with a combination of 0.8µm and 0.45µm filters and ultrafiltration and/or diafiltration, and

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e) purifying the adenovirus with anion exchange and/or size exclusion chromatography.

The claimed invention also includes the use of buffers after step c) free of detergent, MgCl and sucrose; the use of a 0.8-2.0 M NaCl buffer when processing the lysate during ultrafiltration and/or diafiltration; and the use of a buffer comprising at least 2M NaCl in exchange for the solution containing the virus during chromatographic purification.

Zhang et al. teach the culturing of a recombinant adenovirus in host cells followed by the harvesting and lysis of the host cells with multiple techniques (i.e., freeze thaw, sonication and with triton X-100 detergent). Zhang et al. also teach the treatment of the lysate with benzonase in order to remove contaminating DNA from the host cell. Zhang et al. further teach the use of depth filtration or membrane filtration in a tangential flow filtration setup in order to clarify the crude lysate followed by buffer exchange by diafiltration and concentration of the lysate by ultrafiltration. Zhang et al. state diafiltration to exchange buffers is an ideal way to remove sugars, solvents, salts, etc. The buffers employed in the diafiltration contained 1.0 M NaCl or DPBS. Zhang et al. further process the clarified, concentrated viral preparation by purifying the preparation through anion or cation exchange columns, size exclusion column or by using both in chromatography purification steps. During these columns purifications, Zhang et al. use a buffers containing 2.0M NaCl and 0.25 M NaCl in order to process the viral solution (i.e., priming, washing, elution, etc.) Zhang et al. also use a 0.8/0.22  $\mu\text{m}$  filter following depth filtration. However, Zhang et al. do not teach the specific filter combinations or the use of Benzonase prior to cell lysis.

Cook et al. teaches the treatment of yeast cells expressing HPV Virus-Like Particles with benzonase prior to lysis since DNA hydrolysis is more efficient. *See figure 2.*

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Molin et al. teach that adding nucleases prior to lysis of *E. coli* reduces the post lysis viscosity. This Molin et al. also report that by adding the nuclease prior to lysis, less time is required to the necessary consistency in order to harvest the desired proteins. *See column 8, lines 49-62.*

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Zhang et al. in order to use benzonase prior to lysis of host cells, thereby improving the viscosity of the crude lysate. One would have been motivated to do so, given the suggestion by Zhang et al. that Benzonase be used to remove contaminating nucleic acids. There would have been a reasonable expectation of success, given the knowledge that treatment yeast cells with benzonase prior to lysis improves DNA hydrolysis, as taught by Cook et al., and also given the knowledge that by treating *E. Coli* with nuclease prior to lysis improves the isolation of the desired proteins, as taught by Molin et al. Furthermore, even though Zhang et al. do not teach the specific filter combinations of the instant invention, one skilled in the art would be motivated to employ the necessary filters during the membrane filtration step taught by Zhang depending on the size of the virus being producing and the required purity of the finished product. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 7 contain the trademark/trade name Benzonase® and Triton® X-100, respectively. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a nuclease and a detergent, respectively, accordingly, the identification/description is indefinite.

### ***Claim Objections***

Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since claim 33 depends on claim 3 and both claim purifying the virus with at least one chromatography step in step e), claim 33 does not further limit claim 3.

### ***Summary***

No claims are allowed.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/  
Examiner  
Art Unit 1648

/Bruce Campell/  
Supervisory Patent Examiner, Art Unit 1648